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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): QMI-3077

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on 12/23/2009

Signature: Patricia J. English

Typed or printed name: Patricia J. English

Application Number	Filed
10/624,915	07/22/2003

First Named Inventor: D. Russell Pflueger

Art Unit	Examiner
3772	Nihir B. Patel

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 42,515
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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12/23/2009
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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _____ forms are submitted.

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QMI-3077
Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3772
PFLUEGER, D. Russell, et al.	
Serial No.: 10/624,915	Examiner: Nihir B. Patel
Filed: July 22, 2003	
For: APPARATUS AND METHODS FOR TREATING SLEEP APNEA	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ARGUMENTS IN SUPPORT OF PRE-APPEAL REQUEST FOR REVIEW

Dear Sir/Madam:

In accordance with the notice published in the July 12, 2005 Official Gazette, the Assignee of this application hereby requests that a panel of examiners formally review the legal and factual bases of the rejections, before Assignee files an appeal brief. As explained below, it is submitted that the rejections are improper and are without basis, and that the claims now presented in this application define patentable subject matter over the cited prior art.

In the Final Office Action, independent claims 93 and 100 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,328,753 ("the Zammit reference"), and independent claims 52, 82, and 102 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Zammit reference in view of U.S. Patent No. 6,250,307 ("the Conrad reference").

CERTIFICATE OF FACSIMILE TRANSMISSION (37 C.F.R. §1.6 (d))
I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted via fax on the date shown below to the Central FAX Number (571) 273-8300 addressed to the Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

December 23, 2009
Date of facsimile transmission

Patricia J. English

First, as explained on pages 12-13 of Applicants' April 27, 2009 response, the Zammit reference discloses a collapsible nasal-oropharyngeal tube 1 including a tubular mid-section 4 and flared ends 2, 3 that, when expanded, define a lumen 5 intended to provide an unobstructed airway within a nasal passage. Col. 3, line 52 to col. 4, line 6. At least one end 3 of the tube 1 can be coiled or folded as shown in FIGS. 2 and 3 and held by a retaining tie 6. Col. 4, lines 7-13. When collapsed, the tube 1 can be inserted into a patient's nasal passage via the nostril, and then the retaining tie 6 may be broken by pulling a release fiber 7, allowing the collapsed tube 1 to expand in the nasal passage so as to push against the oropharynx and nasal passage walls to maintain upper airway patency. Col. 3, lines 52-57, col. 4, lines 22-27, 45-47; FIG. 7. In this deployed configuration, the proximal end 2 is located at the nostril 9 and the distal end 3 lies at the oropharynx 10 just beyond the soft palate and the release fiber 7 extends from the nostril. Col. 4, lines 34-37. Thus, the Zammit tube 1 is clearly ***not deployable in a C-shaped deployed configuration*** nor is the Zammit tube ***deployable within the oropharyngeal region*** such that ***elongate elements extend laterally across the posterior wall*** and ***end portions bear against lateral walls*** of the oropharyngeal region, as recited in the present claims.

The first error in the Final Office Action occurs on page 2, where the flared ends 2, 3 of the Zammit tube 1 are indicated as being first and second end portions, as claimed. These so-called end portions, however, are ***not deployable in the oropharyngeal region*** nor do they bear against and provide an opening force against the lateral walls of the oropharyngeal region. Instead, the Zammit tube 1 is deployed such that ***one end 2 is located at the nostril 9 and the other end 3 lies at the oropharynx 10***. See FIG. 7. These ends 2, 3 are also incapable of bearing against and providing an opening force against lateral walls of an oropharyngeal region. Instead, the ends 2, 3 are merely biased to open into a flared tubular shape, which would not provide an

opening force against lateral walls of an oropharyngeal region, as explained between pages 14-15 of Applicants' April 27 response. On pages 4-5, the Final Office Action identifies Zammit FIG. 6 as showing a device capable of being deployed as claimed. However, a person of ordinary skill would recognize that the posterior wall of the oropharyngeal region is a particular anatomical region (at the right of and below the lead line 10 in Zammit FIG. 6) and that ***the Zammit tube 1 does not extend laterally across the posterior wall.***

Further, even if the Zammit tube 1 were somehow introduced into the oropharyngeal region and oriented as recited in the present claims, the result would be a tube winding around the oropharyngeal region whose ends are biased to open and flare. Thus, these ends would be biased to flare outwardly into the open area of the oropharyngeal region, thereby potentially obstructing air flow, as well as passage of fluids or food. It would be unreasonable to consider the Zammit tube truly capable of being deployed in this manner.

A second error in the Final Office Action is the conclusion on page 2 that the retaining fibers of the Zammit tube 1 can somehow qualify as one or both of the ***two spaced apart elongated elements*** extending between end portions recited in the present claims. The retaining fibers are clearly not part of the deployed Zammit tube 1 but are merely provided initially to constrain the end 3 from expanding during introduction into a nasal passage. Specifically, the Zammit reference teaches that the retaining fiber 7 is pulled to break a retaining tie 6 and then the fiber 7 extends from the nostril presumably to allow the tube 1 from being removed. Thus, because the retaining fibers are removed when the tube 1 is deployed (otherwise the tubular structure cannot open, which is the entire purpose of the Zammit tube), they cannot constitute elongated elements capable of extending laterally across the posterior wall. Further, the retaining fibers would have no structural integrity and therefore would be incapable of extending laterally

across a posterior wall of an oropharyngeal region to provide an opening force. Thus, the retaining fibers cannot constitute one or both of the elongate elements, as claimed.

The only structure extending between the ends 2, 3 of the Zammit tube 1 is the tubular mid-section 4, which is a singular, unitary tubular structure and does not include two spaced apart elongated members. This is in direct contrast to the arguments on page 4 of the Final Office Action that the Zammit tube 1 can somehow be properly considered multiple elements.

Even if the retaining fiber 7 is intended to be one elongated element and the tube 1 itself the other, these so-called elongated elements are not spaced apart from one another. Instead, since the retaining fibers are tied around the tube, the fibers would not be spaced apart from the tube but would be in intimate contact with the tube, otherwise it would be incapable of constraining the tube for introduction.

A third error in the Final Office Action is the conclusion on page 3 that "an appliance deployable in a C-shaped deployed configuration" is merely a recitation of intended use. Although Applicants submit that this language recites structure of the claimed apparatus and is not merely intended use, this conclusion ignores the fact that claims 52 and 102 are method claims that expressly recite the location and orientation of the apparatus after implantation that are wholly absent from the Zammit reference.

A fourth error in the Final Office Action is discussed on pages 13-14 of Applicants' April 27 response. The Zammit reference does not teach or suggest ***an elongated loop*** comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions, as recited in claim 93, but merely discloses a tube that includes flared ends. Based on the plain meaning and context of the respective teachings, a loop is fundamentally different than a tube.

Turning to the Conrad reference, as explained on pages 15-16 of Applicants' April 27 response, the Conrad reference also fails to teach anything about an appliance comprising an elongated loop comprising two spaced apart elongated elements extending between first and second end portions and sized for introduction into an oropharyngeal region of a human or animal and deployable in a C-shaped deployed configuration, as claimed. In contrast, the Conrad reference merely discloses embedding implants in tissue of the soft palate (i.e., the region 12 identified in Zammit FIGS. 5-7). These implants are incapable of being introduced such that they extend laterally across the posterior and lateral walls of an oropharyngeal region. Thus, even if the Conrad and Zammit references could be properly combined (which Applicants do not concede), the combined references fail to teach or suggest several features of the present claims.

Finally, as explained on pages 19-20 of Applicants' April 27 response, neither reference teaches or suggest anything about ***introducing and releasing an appliance within an oropharyngeal region***. In addition, neither reference teaches or suggests releasing an appliance within the oropharyngeal region such that ***elongated elements extends generally laterally across the posterior wall*** and the first and second ***end portions bear against and provide an opening force against the lateral walls*** of the oropharyngeal region.

In view of the foregoing, it is submitted that the rejections are improper and are without basis, and the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
VISTA IP LAW GROUP LLP

Dated: December 23, 2009

By _____
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